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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/635,725	08/06/2003	Stuart Neil Prince	1324030A	8868

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HESLIN ROTHENBERG FARLEY & MESITI PC
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ALBANY, NY 12203

EXAMINER

FORD, VANESSA L

ART UNIT	PAPER NUMBER
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1645

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	02/08/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

10/635,725

Applicant(s)

PRINCE ET AL.

Examiner

Vanessa L. Ford

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 October 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-16 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-16 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Applicant's Appeal Brief filed October 30, 2006 is acknowledged. Upon further consideration the finality of the Office action mailed October 19, 2005 has been withdrawn and a non-final action is set forth below.

Rejections Maintained

2. The rejection of claims 1 and 7-16 under 35 U.S.C. 102(b) is maintained for the reasons set forth on pages 2-4, paragraph 4 of the previous Final Action.

The rejection was on the grounds Oldroyd et al teach that honeybee colonies were treated with various oxytetracycline hydrochloride (OTC) preparations at the same time of inoculation with *Bacillus larvae* spores. Oldroyd et al teach that colonies were inoculated with a comb (apicultural delivery vehicle) containing larvae sprayed with 20 ml of *Bacillus larvae* (page 692). Claim limitations such as "the composition of claim 1, wherein the inoculum comprises one or more microorganisms that produce one or more antibiotics active against one or more bee pathogens", "the composition of claim 7, wherein the antibiotics are active against at least one of *Melissococcus pluton* and *Paenibacillus larvae subsp. larvae*", "the composition of claim 7, wherein the antibiotics are bacteriolytic" and the composition of claim 7, wherein the antibiotics are the anti-*Melissococcus pluton* and/or the anti-*Paenibacillus larvae subsp. larvae* antibiotics found in *Paenibacillus larvae subsp. pulvifaciens* would be inherent in the teachings of the prior art. The composition of Oldroyd et al anticipate the claimed invention.

Since the Office does not have the facilities for examining and comparing applicant's composition with the composition of the prior art, the burden is on the applicant to show a novel or unobvious difference between the claimed product and the product of the prior art (i.e., that the composition of the prior art does not possess the same material structural and functional characteristics of the claimed composition). See In re Best, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and In re Fitzgerald et al., 205 USPQ 594.

Applicant's arguments

- A. Applicant urges that the primary feature of the claimed composition is an inoculum of one or more microorganisms that are non-pathogenic. Applicant urges that one of skill in the art would not conclude by the reading of Oldroyd et al that *Bacillus larvae* is non-pathogenic.
- B. Applicant urges that inoculation of a bee colony with *B. larvae* would not be able to produce a microflora having therapeutic or prophylactic efficacy against the bee disease as recited in independent claim 1. Applicant urges that Oldroyd et al do not teach the establishment of a protective microflora within the hive or bee colony. Applicant refers to the Evidence Appendix to support their position.

Examiner Response to Applicant's Argument

Applicant's arguments filed October 30, 2006 have been fully considered but they are not persuasive.

- A) It is the Examiner's position that Oldroyd et al teach the claimed invention. Oldroyd et al teach that honey bee colonies were administered oxytetracycline (OTC) preparations and *Bacillus larvae* (*Paenibacillus larvae* subsp. *larvae*). While Applicant has provided evidence that *Bacillus larvae* is a pathogenic organism, it should be remembered that the composition of the prior art comprised *Bacillus larvae* and OTC. Therefore, one of skill in the art could reasonably conclude by the review of the prior art that administering *Bacillus larvae* and OTC would have a protective effect against

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American foulbrood disease (AFB) since Oldroyd et al teach that treatment with the *Bacillus larvae* and OTC delayed development of AFB in 4 hives for 2 months to 1 year and one colony treated did not contract AFB (see the Abstract).

Applicant has provided no side-by-side comparison to show that the claimed product differs from that of the prior art. Therefore, the teachings of Oldroyd et al anticipate the claimed invention.

B) As stated above, Oldroyd et al teach that treatment with the *Bacillus larvae* and OTC delayed development of AFB in 4 hives for 2 months to 1 year and one colony treated did not contract AFB (see the Abstract). Thus, it the Examiner's position that administering *Bacillus larvae* and OTC to honeybee colonies would provide a therapeutic or prophylactic efficacy against bee disease, in particular AFB.

To address Applicant's comment regarding the evidence appendix, it should be noted that Applicant has provided these documents to support their position that *Paenibacillus larvae subsp. larvae* (*Bacillus larvae*) are pathogenic to bees. For example, Hornitzky (Oxytetracycline Sensitivity of *Paenibacillus larvae subsp. larvae*) points out that *Paenibacillus larvae subsp. larvae* are sensitive to OTC and no resistance to OTC appears to have developed over passed 15 to 16 years. This document provides a support as to why the skilled artisan would treat honeybee colonies with OTC preparations at the same time inoculation with *Bacillus larvae* spores as evidence by Oldroyd et al. This may explain why no colonies subsequently develop

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disease signs. Therefore, the composition of the prior art teaches an inoculum of microorganisms that are non-pathogenic to bees.

The composition of the prior art teaches the claimed invention. Applicant has provided no side-by-side comparison to show that the claimed product differs from that of the prior art. Therefore, the teachings of Oldroyd et al anticipate the claimed invention.

New Grounds of Rejection

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 1-16 are rejected under 35 USC 112 second paragraph for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claims recite "whereby a remedial and/or protective microflora is established". It is unclear as to what the applicant is referring? Thus, the metes and bounds of "remedial ... microflora" cannot be ascertained. Clarification as to the meaning of this term is required.

4. Claims 1-16 are rejected under 35 USC 112 second paragraph for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claims recite "susceptible to". It is unclear as to what the applicant is referring? Thus, the metes and bounds of "susceptible to" cannot be ascertained. Clarification as to the meaning of this term is required.

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5. Claims 7-16 are rejected under 35 USC 112 second paragraph for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claims recite "...wherein the inoculum comprises one or more microorganisms that produce one or more antibiotics against one or more be pathogens" (claim 7). It is unclear as to what the applicant is referring? Microorganisms do not produce antibiotics, they produce antibodies when injected with any foreign substance. Antibiotics such as tetracycline are active against microorganisms. Thus, it is unclear as to what Applicant intended by the above cited recitation. Clarification as to the meaning of this term is required.

It should be noted that *Bacillus larvae* is now known as *Paenibacillus larvae* as evidenced by Heyndrickx et al (*Int J Syst Bacteriol*, October 1996, 45(4):988-1003).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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6. Claims 1-16 are rejected under 35 U.S.C. 103(a) as unpatentable over Oldroyd et al (*Aust J Agric Res*, 1989, 40(3), p. 691-698) and in view of Hoopingarner et al (*Apicultural Research*, February, 1988).

The claims are drawn to a composition for the treatment or prophylactic of a bee disease, the composition comprising (a) an inoculum containing one or more microorganisms that are non-pathogenic to bees for producing a microflora having therapeutic or prophylactic efficacy against the bee disease and (b) an apicultural delivery vehicle for delivering the inoculum to a component of a bee hive or a bee colony that is susceptible to or infected with the bee disease whereby a remedial and/or protective microflora is established within the hive or the bee colony.

Oldroyd et al teach that honeybee colonies were treated with various oxytetracycline hydrochloride (OTC) preparations at the same time of inoculation with *Bacillus larvae* spores. Oldroyd et al teach that colonies were inoculated with a comb (apicultural delivery vehicle) containing larvae sprayed with 20 ml of *Bacillus larvae* (page 692).

Oldroyd et al do not specifically teach the claim limitation "the composition of claim 1" wherein the apicultural delivery vehicle is selected from: (a) a patty, (b) a syrup, (c) a drench, (d) a dusting and (e) a paste.

Hoopingarner et al do teach apicultural vehicles used to delivery compounds to bee hives such as is a patty or a dusting or a paste or a spray (page 120).

It would be *prima facie* obvious at the time the invention was made to modify the composition of Oldroyd et al to use apicultural delivery vehicles such as patty, dusting or

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paste or spray because Hooperingarnier et al has taught these are apicultural delivery vehicles used to deliver compounds to bee hives. It would be expected barring evidence to the contrary, that apicultural delivery vehicles such as patty, dusting or paste or spray would effectively deliver compounds to bee hives. It should be remembered that it would be *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to use a suitable apicultural delivery vehicle to deliver the composition comprising *Bacillus larvae* and OTC for the treatment or prophylaxis of a bee disease because Hooperingarnier et al have demonstrated that compositions for the treatment of American foulbrood can be delivered using apicultural delivery vehicles such as a patty, a dusting, a spray or a paste.

It should be remembered that MPEP section 2144.6 states:

It is *prima facie* obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose.... [T]he idea of combining them flows logically from their having been individually taught in the prior art." In re Kerkhoven, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980) (citations omitted) (Claims to a process of preparing a spray-dried detergent by mixing together two conventional spray-dried detergents were held to be *prima facie* obvious.). See also In re Crockett, 279 F.2d 274, 126 USPQ 186 (CCPA 1960).

In the instant case, it would be *prima facie* obvious at the time the invention was made to use apicultural delivery vehicles such as a patty, a dusting, a spray or a paste to deliver the *Bacillus larvae* and OTC compositions of Oldroyd et al to bee hives because Hooperingarnier et al teach that these apicultural delivery vehicles are taught in the art to deliver therapeutic compounds to bee hive to treat bee diseases.

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Status of Claims

7. No claims are allowed.

8. Any inquiry of the general nature or relating to the status of this general application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Papers relating to this application may be submitted to Technology Center 1600, Group 1640 by facsimile transmission. The faxing of such papers must conform with the notice published in the Office Gazette, 1096 OG 30 (November 15, 1989). Should applicant wish to FAX a response, the current FAX number for the Group 1600 is (571) 272-8300.

Any inquiry concerning this communication from the examiner should be directed to Vanessa L. Ford, whose telephone number is (571) 272-0857. The examiner can normally be reached on Monday – Friday from 9:00 AM to 6:00 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffery Siew, can be reached at (571) 272-0787.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov/>. Should you have questions on access to the Private PAIR system, contact the Electronic business Center (EBC) at 866-217-9197 (toll-free).



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February 1, 2007



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